

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference H2347 PCT	FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/EP2004/008205	International filing date (day/month/year) 22.07.2004	Priority date (day/month/year) 24.07.2003	
International Patent Classification (IPC) or national classification and IPC INV. G06T7/00			
Applicant BAUSCH & LOMB INCORPORATED et al			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 15 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. *sent to the applicant and to the International Bureau* a total of sheets, as follows:
 - sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- Box No. I Basis of the report
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-20 as originally filed

Claims, Numbers

1-37 as originally filed

Drawings, Sheets

1/1-11/11 as originally filed

- a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. The amendments have resulted in the cancellation of:
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):
4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

the entire international application,

claims Nos. 17, 27-29

because:

the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 27-29 are so unclear that no meaningful opinion could be formed (specify):

see separate sheet

the claims, or said claims Nos. 17 are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for the said claims Nos.

the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

has not been furnished

does not comply with the standard

the computer readable form

has not been furnished

does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See separate sheet for further details

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Box No. IV Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:
 - restricted the claims.
 - paid additional fees.
 - paid additional fees under protest.
 - neither restricted nor paid additional fees.
2. This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
 - complied with.
 - not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
 - all parts.
 - the parts relating to claims Nos. 1-16, 18-26, 30-37 .

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	3-8, 10-16, 18-26, 30-36
	No: Claims	1, 2, 9, 37
Inventive step (IS)	Yes: Claims	18-23, 30-32, 34, 35
	No: Claims	1-16, 24-26, 33, 36, 37
Industrial applicability (IA)	Yes: Claims	1-16, 18-26, 30-37
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

The following prior art documents will be referred to in the present opinion:

- D1: Nirmaier T, Droste D, Bille J; "Hartmann-Shack sensor ASIC's for real-time adaptive optics in biomedical physics"; July 2002; XP002338274.
- D2: Droste D, Bille J; "An ASIC for Hartmann-Shack wavefront detection"; Feb. 2002; XP001220695.
- D3: Sophia I. Panagopoulou et Al; "Wavefront Customized Ablations With the WASCA Asclepion Workstation"; September/October 2001; XP002338275.
- D4: HOFER H ET AL; "DYNAMICS OF THE EYE'S WAVE ABERRATION"; 2001-03;; XP002338276.
- D5: I. Miro, N. Lopez-Gil, and P. Artal; "Pupil meter and tracking system based in a fast image processing"; 1999; XP8050380.
- D6: LIANG J ET AL; "OBJECTIVE MEASUREMENT OF WAVE ABERRATIONS OF THE HUMAN EYE WITH THE USE OF A HARTMANN-SHACK WAVE-FRONT SENSOR"; 1994-07; XP001182893.
- D7: S.H. BAIK ET AL; "A New centroid detection algorithm for the Shack-Hartmann wavefront sensor"; Oct. 2002.
- D8: Prieto P M et Al; "Analysis of the performance of the Hartmann-Shack sensor in the human eye"; Aug. 2000.

Re Item IV

Lack of unity of invention

Potential Invention 1 (claims 1-13 and 37):

Influence of eye movements on changes in the wavefront

Potential Invention 2 (claims 14-36):

Digital centroid detection

The reasons for which the present application has been deemed to contain two inventions which are not linked such that they form a single general inventive concept, as required by

Rules 13.1, 13.2 and 13.3, PCT are as follows:

A. Prior art disclosure:

The following technical features are disclosed in document D1:

A.1. Claim 1:

A method for wavefront analysis, comprising:

- a) acquiring a plurality of wavefront images of light exiting a pupil of an eye, wherein each of the images includes a displaced centroid that is indicative of wavefront measurement information of the eye (**D1: section I.B. "Wave-front Aberrations"**); and
- b) calculating and displaying the wavefront measurement information online for a selected aberration order (**D1: section III.A. "HSSX": 2nd par.** (cf. for more details the document D2, cited by D1 as ref. [9]: **section V.C. "Measurement of Optical Wavefronts"**)).

A.2. Claim 2:

The method of claim 1, comprising acquiring the images at a rate equal to or greater than 10hz (**D1: section II. "an ASIC concept for Hartmann-Shack Sensors", introductory part**).

A.3. Claim 9:

The method of any of claims 1 to 8, wherein the wavefront measurement information is selected to correspond to one of the second through the 10th Zernike aberration orders or optical equivalents thereof (**D1: section I.B. "Wave-Front Aberrations": 2nd par.**).

A.4. Claims 3, 4, 7 and 8:

The subject matter of the claims 3, 4, 7 and 8 is merely a choice of implementation, that

the person skilled in the art would make according to the circumstances without exercise of inventive-skill (cf. for instance **D2: section V.C. "Measurement of Optical Wavefronts"** or **D6: table 3**).

A.5. Claims 5, 6 and 13:

It is well known that the Zernike coefficients depend on the pupil size (cf. for instance **D3: section "Patients and Methods": 2nd par.** or **D6: table 3** where the aberration values are calculated for a given pupil size). Consequently, the subject matter of the claims 5, 6 and 13 is merely a choice of implementation, that the person skilled in the art would make according to the circumstances without exercise of inventive-skill.

A.6. Claim 37:

All the technical features of the claim 37 are either explicitly or implicitly disclosed by D1.

Remark:

The documents D2, D3 and D6 are cited as examples showing some general knowledge of the person skilled in the art.

B. Potential Inventions:

B.1. Potential Invention 1:

The technical features of claim 10 are not anticipated by D1 and can be seen to make a contribution over this prior art (Special Technical Features (STF), Rule 13.2 PCT):

acquiring a corresponding pupil image of the eye for each wavefront image;
determining at least one of position data, size data, shape data, and geometric characterization data of the pupil in each pupil image; and
displaying at least one of the pupil images and the corresponding pupil image data online.

From these STF, the objective problem to be solved by the 1st invention can be construed as:

how to evaluate the influence of eye movements on wavefronts variations?

B.2. Potential Invention 2:

The additional technical features (wrt claim 1) of claim 14, the technical features of the claim 15 or the technical features of the claim 36 can be seen to make a contribution over this prior art (Special Technical Features (STF), Rule 13.2 PCT).

- a) acquiring an $X \times Y$ size image represented by a variable pixel signal intensity;
- b) compressing the $X \times Y$ size image to an $X/n \times Y/m$ size image, where n, m equal any integers and $X/n, Y/m$ are integer values;
- c) determining a background intensity for any position in the compressed image and subtracting this background from the compressed image;
- d) detecting a plurality of approximately positioned centroids in the background-subtracted compressed image;
- e) iterating step (d) until approximate positions of a desired plurality of centroids are detected;
- f) converting the approximate position of the desired plurality of centroids into more exact positions in the $X \times Y$ size image, whereby every centroid position in the image has been identified.

From these STF the objective problem to be solved by the 2nd invention can be construed as:

How to perform digital centroid detection?

C. Conclusion:

The above analysis shows that the special technical features of invention 1 (claims 1-13 and 37) are not the same as those of invention 2 (claims 14-36) and since they can be implemented independently, they are not corresponding to those of invention 2 either.

Therefore, the two groups of claims are not linked by common nor corresponding special technical features and define two different inventions, not linked by a single general inventive concept.

Furthermore, their objective problems are not the same nor corresponding.

Consequently, neither the objective problem underlying the subjects of the (two) claimed inventions, nor their solutions defined by the (special) technical features allow for a relationship to be established between the said inventions, which involves a single general inventive concept.

In conclusion, the application, does not meet the requirements of Unity of Invention as defined in Rules 13.1 and 13.2 PCT.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Novelty related objections:

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 2, 9 and 37 is not new in the sense of Article 33(2) PCT (cf. sections A.1.-A.3. and A.6.).

2. Inventive-step related objections:

Negative Assessment:

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 3-8 and 10-16, 24-26, 33 and 36 does not involve an inventive step in the sense of Article 33(3) PCT.

1. Claims 3-8 and 13:

The subject-matter of claims 3-8 and 13 does not involve an inventive step in the sense of Article 33(3) PCT (cf. sections A.4. and A.5.).

2. Claims 10-12:

The following features of claim 10 are not disclosed by document D1:

acquiring a corresponding pupil image of the eye for each wavefront image; determining at least one of position data, size data, shape data, and geometric characterization data of the pupil in each pupil image; and displaying at least one of the pupil images and the corresponding pupil image data online.

The problem to be solved by the present invention may therefore be regarded as:

how to evaluate the influence of eye movement on changes in the wavefront (cf. desc. p.19 l.18-19)?

The features of "acquiring a corresponding pupil image of the eye for each wavefront image; determining at least one of position data, size data, shape data, and geometric characterization data of the pupil in each pupil image" are described in the document D4 (D4: section 3.B.2. "Eye Movements" and D5 (cited by D4 as reference 18): **Abstract** and section 3.2 "Eye Tracking") as providing the same advantages as in the present application.

The skilled person would therefore regard it as a normal option to include these features in the method described in document D1 in order to solve the problem posed.

The additional feature of "displaying at least one of the pupil images and the corresponding pupil image data online" (resp. the subject-matter of claims 11 and 12) is merely a choice of implementation, that the person skilled in the art would make according to the circumstances without any exercise of inventive-skill.

3. Claims 15 and 36:

The following features of the claim 15 are disclosed either explicitly or implicitly by D7 (**D7: section 2: par.2-4**):

An algorithm for centroid detection in an image, comprising:

- a) acquiring an $X \times Y$ size image represented by a variable pixel signal intensity;
- b) compressing the $X \times Y$ size image to an $X/n \times Y/m$ size image, where n, m equal any integers and $X/n, Y/m$ are integer values;
- c) determining a background intensity for any position in the compressed image and subtracting this background from the compressed image;
- d) detecting a plurality of approximately positioned centroids in the background-subtracted compressed image;
- f) converting the approximate position of the desired plurality of centroids into more exact positions in the $X \times Y$ size image, whereby every centroid position in the image has been identified.

In D7 (**D7: section 2: par.2-4**), it is obvious that the equation (2) may be used in both the rough center position and the precise center position calculations, however the details (step (e) of the claim 1) of the center calculation are not disclosed.

Such details of the center calculation are however described in document D8 (**D8: section 3.c. par.3**) as providing the same advantages as in the present application. The skilled

person would therefore regard it as a normal design option to include these features in the algorithm described in document D7 yielding the subject-matter of claim 15.

Therefore the subject-matter of claim 15 (resp. 36) is not inventive.

4. Claim 14:

It is clear that the wavefront measurement information calculation of the claim 15 may be used in the measurement of human eye aberrations. The subject-matter of the claim 14 is therefore considered not inventive.

5. Claims 16 and 33:

Following the section concerning the claim 15, the subject-matter of the claim 16 (resp. 33) is also considered not inventive.

6. Claims 24-26:

The combination of features present in the claims 24-26 is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill.

Positive Assessment:

Despite some missing essential features (cf. Re Item VIII), the underlying subject-matter of the claims 18-23, 30-32, 34 and 35 meets the requirements of the PCT with respect to novelty and inventive step:

3. Industrial applicability:

The subject-matter of the claims 1-16, 18-26 and 30-37 relates to image processing methods applied to the field of eye measurements and is therefore industrially applicable.

Re Item III and VIII

Certain observations on the international application

The claims 17 and 27-29 are not examined in the present opinion for the following reasons:

claim 17:

The subject-matter of the claim 17 is not supported by the description (cf. desc. p.10 l.11-18) as required by Article 6 PCT.

claim 27:

The way the extrapolation of the claim 27 (cf. also desc. p.7 l.17-19) is carried out is not clear.

Remarks concerning the claims 18-23 and 30:

claims 18-23:

Claim 18 (resp.19-23) does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement

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of the underlying problem, without providing the technical features necessary for achieving this result.

It seems that the features of the claim 34 are essential to the definition of the subject-matter of the claim 18 (resp. 19-20 and 23).

claim 30:

The step f) in the claim 30 is not clearly defined.

Therefore, claim 30 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

It seems that the features of the claim 31 are essential to the definition of the subject-matter of the claim 30.